

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:	)
GAO, et al.	) EXAMINER: Unknown
SERIAL NUMBER: 10/633,390	<i>)</i> ) ) GROUP ART UNIT:  Unknowr
FILED: JULY 31, 2003	) )
TITLE: PHARMACEUTICAL DOSAGE FORM CAPABLE OF MAINTAINING STABLE DISSOLUTION PROFILE UPON STORAGE	, ) ) )

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97(b)

Commissioner for Patents P.O. BOX 1450 Alexandria VA 20231-1450

Dear Sir:

This Information Disclosure Statement (IDS) is filed in accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§ 1.97-1.98, as supplemented by MPEP § 609. Presentation of documents listed on enclosed Form PTO-1449 is not an admission that any listed document is prior art under 35 U.S.C. No patents or publications reviewed or considered by the inventors or undersigned attorney is believed to constitute a *prima facie* case of unpatentability.

This IDS is filed under the provisions of § 1.97(b), as it is believed submitted prior to the mailing of a first Office Action on the merits. Accordingly, no fee is believed payable in respect of this IDS. However, if it is determined that a fee is payable, please charge such fee to Deposit Account No 19-1025.

Respectfully submitted,

Kenton N. Fedde, Reg. No. 54,701

Attorney for Applicant

Telephone: (314) 274-5402

Sheet 1 of 2

ORM PTO-1449 U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE

TA TRADE

ATTY. DOCKET NO.: 01260/2/US APPLICATION NO.: 10/633,390

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

INVENTOR: GAO, et al.

Filed: JULY 31, 2003

Group:

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

Examiner		Document			ŀ		Filing Date If	
Initial		Number	Date	Name	Class	Subclass	Appropriate	
	A1	3,592,945	13 July 1971	Pesch.	252	316	07 March 1968	
-	A2	3,656,997	18 April 1972	Cordes.	117	73	11 May 1970	
	A3	4,231,211	04 November 1980	Strampfer et al.	53	452	10 October 1978	
	A4	4,263,251	21 April 1981	Voegle.	264	503	03 March 1980	
:=	A5	4,403,461	13 September 1983	Goutard et al.	53	282	19 February 1981	
	A6	4,609,403	02 Septmeber 1986	Wittwer et al.	106	122	12 March 1984	
	A7	4,705,658	10 November 1987	Lukas.	264	25	07 April 1986	
	A8	4,720,924	26 January 1988	Hradecky et al.	34	1	03 November 1986	
	A9	4,744,988	17 May 1988	Brox.	424	456	17 December 1986	
	A10	4,756,902	12 July 1988	Harvey et al.	424	454	25 July 1986	
-	A11	4,804,542	14 February 1989	Fischer et al.	424	456	09 April 1987	
	A12	4,884,602	05 December 1989	Yamamoto et al.	141	242	17 June 1988	
	A13	4,892,766	09 January 1990	Jones.	428	36.4	08 September 1988	
	A14	5,146,758	15 September 1992	Herman.	62	62	04 March 1991	
	A15	5,254,294	19 October 1993	Wunderlich et al.	264	4	30 April 1992	
	A16	6,238,616	29 May 2001	Ishikawa et al.	264	553	14 December 1998 08 February 1999	
	A17	6,260,332	17 July 2001	Takayanagi.	53	454		
	A18	6,350,468	26 February 2002	Sanso.	424	456	14 December 1998	

## FOREIGN PATENT DOCUMENTS

Examiner							Transla	ıtion
Initial		Document Number	Date	Country	Class	Subclass	Yes	No
	B1	WO 84/00919	15 March 1984	PCT				
	B2	WO 85/04100	26 September 1985	PCT				
	B3	WO 92/15828	17 September 1992	PCT				

EXAMINER

**DATE CONSIDERED** 

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

./	SIPE
	DEC 1 1 2003 &
E.	TRAD TORM

ORM PTO-1449

U.S. DEPARTMENT OF COMMERCE, PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.: **01260/2/US**  APPLICATION NO.: **10/633,390** 

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

INVENTOR: GAO, et al.

Filed: JULY 31, 2003 Group:

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Examiner Initial		
	C1	Industrial Solvents Handbook; 5th ed., p. 392, Noyes Data Corporation, Westwood, NJ; Flick (1998)
	C2	Pharmaceutical Dosage Forms and Drug Delivery Systems; 6th ed., pp 1646-1647, Williams & Wilkins, Baltimore, MD Ansel et al. (1995)
	C3	Remington: The Science and Practice of Pharmacy; 19th Ed., pp 1646-1647, Mack Publishing Co. Easton. PA
	C4	United States Pharmacopoeia; 24th ed., pp 2254-2298; 2299-2304, (USP 24), 2000
	C5	Collaborative Development of Two-Tier Dissolution Testing for Gelatin Capsules and Gelatin-Coated Tablets using Enzyme-Containing Media, Stimuli to the Revision Process; Pharmacopeial Forum, Vol. 25, No. 5, pp 7045- 7050, SeptOct. 1998
	C6	Singh et al., Alteration in Dissolution Characteristics of Gelatin Containing Formulations; Pharmaceutical Technology, 26 (4), 36-58, April 2002

EXAMINER

**DATE CONSIDERED** 

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(Form PTO-1449)